

CLAIMS

What is claimed is:

1. A method of promoting smoking cessation in a human comprising administering to the human an effective amount of reboxetine in combination with
5 administration of an effective amount of a smoking-cessation enhancing agent.
2. The method of claim 1, wherein the reboxetine is in the form of racemic mixture of the S,S- and R,R-enantiomers, or pharmaceutically acceptable salts thereof, in any ratio.
3. The method of claim 1, wherein the reboxetine is in the form of pure or
10 substantially pure S,S-enantiomer or pharmaceutically acceptable salts thereof.
4. The method of claim 2, wherein the effective amount of reboxetine is from about 0.1 mg to about 20 mg per patient per day.
5. The method of claim 2, wherein the effective amount of reboxetine is from about 0.1 mg to about 10 mg per patient per day.
- 15 6. The method of claim 2, wherein the effective amount of reboxetine is from about 0.2 mg to about 5 mg per patient per day.
7. The method of claim 2, wherein the effective amount of reboxetine is from about 0.3 mg to about 3 mg per patient per day.
8. The method of claim 3, wherein the effective amount of reboxetine is from
20 about 0.1 mg to about 6 mg per patient per day.
9. The method of claim 3, wherein the effective amount of reboxetine is from about 0.2 mg to about 4 mg per patient per day.
10. The method of claim 3, wherein the effective amount of reboxetine is from about 0.3 mg to about 3 mg per patient per day.
- 25 11. The method of claim 1 wherein the reboxetine and the smoking-cessation enhancing agent are administered separately.
12. The method of claim 1 wherein the reboxetine and the smoking-cessation enhancing agent are administered in a single composition.
13. The method of claim 1, wherein the smoking-cessation enhancing agent is
30 nicotine, an antidepressant, an anxiolytic, a nicotine receptor antagonist, an opioid antagonist, or the mixture thereof.
14. The method of claim 1 wherein smoking-cessation enhancing agent is nicotine.

15. The method of claim 14 wherein the nicotine is in a dosage form of transdermal patch, chewing gum, lozenge, capsule, tablet, inhalant, or nasal spray.
16. The method of claim 1 wherein the smoking-cessation enhancing agent is an antidepressant.
- 5 17. The method of claim 16 wherein the antidepressant is selected from the group consisting of bupropion, doxepin, amitriptyline, clomipramine, desipramine, imipramine, nortriptyline, protriptyline, trimipramine, fluoxetine, fluvoxamine, paroxetine, sertraline, phenelzine, tranylcypromine, amoxapine, maprotiline, tomoxetine, duloxetine, trazodone, nefazodone, venlafaxine, mirtazapine, and
10 pharmaceutically acceptable salts of any said antidepressant.
18. The method of claim 16 wherein the antidepressant is doxepin or a pharmaceutically acceptable salt thereof.
19. The method of claim 16 wherein the antidepressant is bupropion or a pharmaceutically acceptable salt thereof.
- 15 20. The method of claim 1 wherein smoking-cessation enhancing agent is an anxiolytic.
21. The method of claim 20 wherein the anxiolytic is a benzodiazepine.
22. The method of claim 20 wherein the anxiolytic is alprazolam, chlordiazepoxide, clorazepate, diazepam, halazepam, lorazepam, oxazepam,
20 prazepam, midazolam, clonazepam, or pharmaceutically acceptable salts thereof.
23. The method of claim 20 wherein the anxiolytic is buspirone, hydroxyzine, meprobamate, or pharmaceutically acceptable salts thereof.
24. The method of claim 20 wherein the anxiolytic is buspirone HCl.
25. The method of claim 1 wherein smoking-cessation enhancing agent is a
25 nicotine receptor antagonist.
26. The method of claim 25 wherein the nicotine receptor antagonist is selected from mecamlamine, dihydro-beta-erythroidine, tubocurarine chloride, d-tubocurarine, amantadine, pempidine, erysodine, chlorisondamine, hexamethonium, trimethaphan camsylate, and a pharmaceutically acceptable salt of any said nicotine
30 receptor antagonist.
27. The method of claim 25 wherein the nicotine receptor antagonist is mecamlamine or a pharmaceutically acceptable salt thereof.

28. The method of claim 1 wherein the smoking-cessation enhancing agent is an opioid antagonist.
29. The method of claim 28 wherein the opioid antagonist is naltrexone, naloxone, nalmefene, or a pharmaceutically acceptable salt of any said opioid antagonist.
- 5 30. The method of claim 28 wherein the opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.
31. A pharmaceutical composition for administration to a human for promoting smoking cessation, said composition comprising an effective amount of reboxetine and an effective amount of a smoking-cessation enhancing agent.
- 10 32. The pharmaceutical composition of claim 31 wherein the smoking-cessation enhancing agent is nicotine, an antidepressant, an anxiolytic, a nicotine receptor antagonist, an opioid antagonist, or the mixture thereof.
33. The pharmaceutical composition of claim 31 wherein the smoking-cessation enhancing agent is nicotine.
- 15 34. The pharmaceutical composition of claim 31 wherein the smoking-cessation enhancing agent is an antidepressant.
35. The pharmaceutical composition of claim 34 wherein the antidepressant is selected from the group consisting of bupropion, doxepin, amitriptyline, clomipramine, desipramine, imipramine, nortriptyline, protriptyline, trimipramine, fluoxetine, 20 fluvoxamine, paroxetine, sertraline, phenelzine, tranylcypromine, amoxapine, tomoxetine, duloxetine, maprotiline, trazodone, nefazodone, venlafaxine, mirtazapine, and pharmaceutically acceptable salts of any said antidepressant.
36. The pharmaceutical composition of claim 34 wherein the antidepressant is doxepin or a pharmaceutically acceptable salt thereof.
- 25 37. The pharmaceutical composition of claim 34 wherein the antidepressant is bupropion or a pharmaceutically acceptable salt thereof.
38. The pharmaceutical composition of claim 31 wherein smoking-cessation enhancing agent is an anxiolytic.
39. The pharmaceutical composition of claim 38 wherein the anxiolytic is a 30 benzodiazepine.
40. The pharmaceutical composition of claim 38 wherein the anxiolytic is alprazolam, chlordiazepoxide, clorazepate, diazepam, halazepam, lorazepam,

oxazepam, prazepam, midazolam, clonazepam, or pharmaceutically acceptable salts thereof.

41. The pharmaceutical composition of claim 38 wherein the anxiolytic is buspirone, hydroxyzine, meprobamate, or pharmaceutically acceptable salts thereof.

5 42. The pharmaceutical composition of claim 38 wherein the anxiolytic is buspirone HCl.

43. The pharmaceutical composition of claim 1 wherein smoking-cessation enhancing agent is a nicotine receptor antagonist.

44. The pharmaceutical composition of claim 43 wherein the nicotine receptor
10 antagonist is selected from mecamylamine, dihydro-beta-erythroidine, tubocurarine chloride, d-tubocurarine, amantadine, pempidine, erysodine, chlorisondamine, hexamethonium, trimethaphan camsylate, and a pharmaceutically acceptable salt of any said nicotine receptor antagonist.

45. The pharmaceutical composition of claim 43 wherein the nicotine receptor
15 antagonist is mecamylamine or a pharmaceutically acceptable salt thereof.

46. The pharmaceutical composition of claim 1 wherein the smoking-cessation enhancing agent is an opioid antagonist.

47. The pharmaceutical composition of claim 46 wherein the opioid antagonist is
20 naltrexone, naloxone, nalmefene, or a pharmaceutically acceptable salt of any said opioid antagonist.

48. The pharmaceutical composition of claim 46 wherein the opioid antagonist is naltrexone or a pharmaceutically acceptable salt thereof.

49. The method of claim 19 wherein the effective amount of bupropion or a pharmaceutically acceptable salt thereof is from about 40 mg to about 250 mg per day.

25 50. The method of claim 19, wherein the effective amount of bupropion or a pharmaceutically acceptable salt thereof is from about 50 mg to about 200 mg per day.

51. The method of claim 19, wherein the effective amount of bupropion or a pharmaceutically acceptable salt thereof is from about 75 mg to about 150 mg.

52 The method of claim 14 wherein the effective amount of nicotine is from
30 about 7 mg to about 42 mg per day.

53. The method of claim 14 wherein the effective amount of nicotine is from about 3 mg to about 21 mg per day.

54. The composition of claim 31, wherein the reboxetine is in the form of racemic mixture of the S,S- and R,R-enantiomers, or pharmaceutically acceptable salts thereof, in any ratio.

55. The composition of claim 31, wherein the reboxetine is in the form of pure or
5 substantially pure S,S-enantiomer or pharmaceutically acceptable salts thereof.